

REMARKS

Claims 1-36 and 38 are the only claims pending. Claims 3-20, 27-32 and 38 are cancelled due to a restriction requirement.

Claim 22 is currently amended to delete the term "and/or" and to improve clarity.

Claims 35 and 36 are currently amended to restrict the crystalline polymorphic form to form A which is the subject of the current restriction requirement.

No new matter has been added.

Claims 1-2, 21-26 and 33-36 are presented for reconsideration.

In the Specification

A paragraph is added at the top of page one directly after the title identifying the parent application from which the present application is derived.

Claim Rejections 35 USC 112, First Paragraph

1. Claims 1 and 2 rejected under 35 USC, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The Examiner rejects instant claims 1 and 2 under 35 USC 112, first paragraph for failing to comply with the written description requirement. Specifically, the Examiner reasons that the full "fingerprint" of x-ray peaks should be included rather than the 8 peaks of instant claim 1, or that an explanation should be given in the specification why this is not necessary.

The art cited in this regard (Byrns, page 63) relates to the practical method of evaluating x-ray diagrams. It does not teach that correlation of each and every peak of such a diagram is necessary,

since the person skilled in this art knows very well that an x-ray diagram, just like any other experimental diagram in science, may contain peaks unrelated to the subject ("noise"), and the more intensive peaks are the more reliable ones.

These more reliable peaks (intensity strong or very strong) have been combined in instant claim 1. The explanation for this selection is evident for the person skilled in the art, reciting an explanation for this procedure in the specification thus is unnecessary.

Including instant claim 2 into this rejection appears to be the result of a reading error, since instant claim 2 does not refer to specific peaks but to the full x-ray diagram of Figure 1 and thus appears to fully comply with the Examiner's requirement.

The objection thus appears unjustified and, as such, instant claims 1 and 2 are in full compliance with the written description requirement recited by the Examiner.

2. Claim 22 is rejected under 35 USC, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 22 is currently amended to delete the term "and/or" and to improve clarity.

The Applicants therefore aver that the 35 USC 112, first paragraph, rejections are addressed and are overcome.

Claim Rejections 35 USC 112, Second Paragraph

Claims 23, 35 and 36 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 23 is rejected because the Examiner is unfamiliar with the term "non-solvent". The Applicants respectfully disagree.

The term "non-solvent" seems fairly clear in the paragraph bridging pages 12 and 13 of the instant specification that the non-solvent role is one of a trituration solvent. However, the term "non-solvent" is known in the art; for example, US 4,182,850 describes a polycarbonate process employing a non-solvent.

2. Claims 35 and 36 are rejected because of the phrase "crystalline polymorph form".

Claims 35 and 36 are currently amended to restrict the crystalline polymorphic form to form A which is the subject of the current restriction requirement.

The Applicants therefore aver that the 35 USC 112, second paragraph, rejections are addressed and are overcome.

Claim Rejections – 35 USC 102(b)

Claims 1-2, 25-26 and 35-36 are rejected under 35 USC 102(b) as being anticipated by Patel (US 6,084,103).

Claims 35 and 36 are currently amended to restrict the crystalline polymorphic form to form A which is the subject of the current restriction requirement.

Patel is totally silent as to the crystal form of the solid product, Zolmitriptan. In addition, Patel's process actually dissolves the title compound in Stages 6A & 6B in ethyl acetate (6A) or a 10% mixture of ethanol in ethyl acetate.

Instant claims 25 and 26 either disperse amorphous Zolmitriptan or suspend crystalline Zolmitriptan in a solvent and does not dissolve Zolmitriptan as taught in Patel.

Moreover, Patel neither teaches any specific crystal form nor suggests to do so; therefore, Patel does not anticipate the instant invention.

The present 35 USC 102(b) rejection is addressed and is overcome.

Claim Rejections – 35 USC 103(a)

Claims 21-24 and 33-34 are rejected under 35 USC 103(a) as being unpatentable over Patel (US 6,084,103), and further in view of Armarego et al. (Purification of Laboratory Chemicals (4th edition), 1997, Elsevier) and H.G. Brittain Polymorphism in Pharmaceutical Solids, V. 95, New York, New York, Marcel Dekker, Inc. 1999.

As the Examiner points out in page 9 of the Office Action, Patel teaches ethyl acetate and a 10% mixture of ethanol in ethyl acetate for crystallization and recrystallization of Zolmitriptan. In claims 21-24, ethyl acetate is among the list of solvents that is excluded in the instant invention. In Armarego et al. (pages 12-13) discloses a general method for recrystallization and purification on page 12 and later discusses the best solvents for use in recrystallization. Ethyl acetate, as taught in Patel, fits all of the characteristics (a)-(f) for a good solvent choice in recrystallization. One skilled in the art would use these combined teachings and arrive at the choice of ethyl acetate to use for the purification of Zolmitriptan; therefore, the instant novel crystal form would have gone undiscovered.

Without knowledge of the instant invention said invention is unobvious for a person skilled in the art because without teaching and motivation in the cited prior art or any other useful hints and without substantial testing no person skilled in the art could expect the advantageous properties of the instant invention.

In consequence, the Applicants aver that combined cited art does not teach or suggest the instant invention.

The present 35 USC 103(a) rejection is addressed and is overcome.

The Examiner is kindly requested to reconsider and to withdraw the present objections and rejections.

Applicants submit that the present claims are in condition for allowance and respectfully request that they be found allowable.

Respectfully submitted,



for

Mervin G. Wood, Ph.D
Agent for Applicants
Reg. No. 56,711

TYLER REVENSON
Reg. No. 46388

Ciba Corporation
Patent Department
540 White Plains Road
P.O. Box 2005
Tarrytown, NY 10591-9005
Phone: (914) 785-7113
Fax (914) 785-7102
MGW23017A1